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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/123,220	07/23/98	LINDEN	B 513.12-0036

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QM31/0414

EXAMINER

MCDERMOTT, C

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 04/14/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/121,368

Applicant(s)
Lindin et al.

Examiner
Corrine McDermott

Group Art Unit
3763



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-162 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-162 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Jul 23, 1998 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Reissue Applications

The reissue oath/declaration filed with this application is defective (see 37 CFR 1.175 and MPEP § 1414) because of the following:

It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The post office address should include the ZIP Code designation.

✓ It does not state whether the inventor is a sole or joint inventor of the invention claim

Applicant's attention is directed to MPEP 602 which states as follows:

When joint inventors execute separate oaths or declarations, each oath or declaration should make reference to the fact that the affiant is a joint inventor together with each of the other inventors indicating them by name. This may be done by stating that he or she does verily believe himself or herself to be the original, first and joint inventor together with "A or A & B, etc." as the facts may be.

✓ The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a).

✓ It does not identify the city and state or foreign country of residence of each inventor.

In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

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Claims 1-162 are rejected as being based upon a defective declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

Drawings

/ The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plurality of penetrating members, as set forth in claims 62 and 95, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims ~~70~~, ~~71~~, ~~78~~, ~~79~~, 140, 141 and 151-154 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not provide support for *rotary motion* of the penetrating member about a pivot point, for a stylet connected to the tissue penetrating member, or for a metabolic intermediate.

✓ Claims 96-98 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the tissue penetrating member to be heated, cooled, or adapted for vibratory motion.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 57-162 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 57, 74, 82, 86, 91, 103, 110, 116, 120, 125, 130, 132, 140, 142, 143, 147, 151, and 155 are found to be incomplete because there is set forth no structural communication or relationship between the elongate catheter body, the tissue penetrating member and the actuator.

Claims 103, 11, 116, 120, 125, 120, 132, 140, 142, 143, 147, 151 and 155 are further found to be indefinite because it is unclear how they recite methods for treating cardiac tissue when there are no steps set forth reciting placement of the device within or at cardiac tissue.

In claim 67 “a proximal portion” is merely inferentially included in the claim and not positively recited.

In claims 75 and 83 “a constraining lumen” is merely inferentially included in the claim and not positively recited.

In claim 117 “a restraint lumen” is merely inferentially included in the claim and not positively recited.

There is no antecedent basis in the claims for “the genetic material” or “the tissue” of claim 133.

There is no antecedent basis in the claims for “the cardiac tissue” of claims 134, 135, 137, 138, and 160-162.

There is no antecedent basis in the claims for “the wall of a coronary vessel”.

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 57, 59-63, 65-69, 72-74, 80-81, 86, 88-91, 93-103, 105-110, 114, 115, 120, 122-125, 128 and 129 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lemelson.

Lemelson discloses a therapeutic device, which as seen in figures 5 and 6, includes a catheter body having a penetrating member 61 therein for delivery drugs to a specific site in the body. As set forth in column 1 lines 14 and 35-40, the device is for use in a vein, artery, or the tissue of an organ, duct or tumor. Column 6 lines 36-37 set forth that the penetrating member can be heated or cooled, and is clearly adapted for vibratory motion. With reference to the embodiment of figures 1-3, it is set forth in column 7 line 44, that a plurality of penetrating members can be attached thereto.

Claims 57, 59-61, 63, 65-69, 72-74, 80-81, 86, 88-91, 93, 94, 99-103, 105-110, 114, 115, 120, 122-125, 128 and 129 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Imran.

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Imran discloses a therapeutic device which includes a catheter body having penetrating member 36. With reference to column 1 line 27, the device is used for the delivery of a plurality of chemicals to sites such as the myocardium, note column 5 line 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 130-159 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson.

Lemelson discloses the invention substantially as claimed, the method of using a therapeutic device for injecting select quantities of medication and drugs through a penetrating member into body tissue. Lemelson does not disclose, however, the specific types of drugs as claimed. In view of the teaching, it would have been an obvious matter of design choice to one of ordinary skill in the art, to inject the drugs as claimed through the penetrating member of Lemelson since Applicant has not disclosed that any one drug solves any stated problem, or is any more critical than any other drug.

Claims 130-162 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran.

Imran discloses the invention substantially as claimed, the method of using a therapeutic device for injecting select quantities of medication and drugs through a penetrating member into

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body tissue, such as cardiac tissue. Imran does not disclose, however, the specific types of drugs as claimed. In view of the teaching, it would have been an obvious matter of design choice to one of ordinary skill in the art, to inject the drugs as claimed through the penetrating member of Imran since Applicant has not disclosed that any one drug solves any stated problem, or is any more critical than any other drug.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dafoe discloses a device analogous to that as claimed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Corrine McDermott, whose telephone number is (703) 308-2111. The Examiner can normally be reached on Monday through Thursday from 7:00 AM to 4:30 PM. The Examiner can also be reached on alternate Fridays.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. The fax phone number for this Group is (703) 305-3590.



Corrine M. McDermott
Primary Examiner
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